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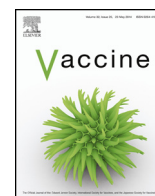
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# Pediatric immunization-related safety incidents in primary care: A mixed methods analysis of a national database



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## ABSTRACT

**Background:** Children are scheduled to receive 18–20 immunizations before their 18th birthday in England and Wales; this approximates to 13 million vaccines administered per annum. Each immunization represents a potential opportunity for immunization-related error and effective immunization is imperative to maintain the public health benefit from immunization. Using data from a national reporting system, this study aimed to characterize pediatric immunization-related safety incident reports from primary care in England and Wales between 2002 and 2013.

**Methods:** A cross-sectional mixed methods study was undertaken. This comprised reading the free-text of incident reports and applying codes to describe incident type, potential contributory factors, harm severity, and incident outcomes. A subsequent thematic analysis was undertaken to interpret the most commonly occurring codes, such as those describing the incident, events leading up to it and reported contributory factors, within the contexts they were described.

**Results:** We identified 1745 reports and most ( $n = 1077$ , 61.7%) described harm outcomes including three deaths, 67 reports of moderate harm and 1007 reports of low harm. Failure of timely vaccination was the potential cause of three child deaths from meningitis and pneumonia, and described in a further 113 reports. Vaccine administration incidents included the wrong number of doses ( $n = 476$ , 27.3%), wrong timing ( $n = 294$ , 16.8%), and wrong vaccine ( $n = 249$ , 14.3%). Documentation failures were frequently implicated. Socially and medically vulnerable children were commonly described.

**Conclusion:** This is the largest examination of reported contributory factors for immunization-related patient safety incidents in children. Our findings suggest investments in IT infrastructure to support data linkage and identification of risk predictors, development of consultation models that promote the role of parents in mitigating safety incidents, and improvement efforts to adapt and adopt best practices from elsewhere, are needed to mitigate future immunization-related patient safety incidents. These priorities are particularly pressing for vulnerable patient groups.

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**Abbreviations:** NRLS, National Reporting and Learning System; WHO, World Health Organization.

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## 1. Introduction

Each immunization represents a potential opportunity for immunization-related safety incidents, and given their prevalence and potential preventability the World Health Organization (WHO) has recognized this as a priority area for healthcare improvement [1]. Without address, population-level protection could be compromised, national campaign efforts to promote uptake hindered, and the trust of patients and families reduced [1,2].

Reviews of patient medical records estimate 27–35% of immunizations involve an error [3–6]. Analysis of patient safety incident reports, such those within the US MedMARx reporting system, have suggested additional doses, the wrong immunization, and the wrong dose given are the main types of errors involved [7]. Further, surveillance systems collecting information about adverse drug reactions, such as the Vaccine Adverse Event Reporting System, have also identified common sources of errors, but they primarily focus and receive reports on the health problems, illnesses or symptoms experienced by patients following immunization [8,9]. Despite those insights, analyses of such reports are often limited by the lack of comprehensiveness of reports.

Whilst previous studies have classified immunization-related safety incidents in terms of their type [7,9,10], few studies have comprehensively explored the underlying factors contributing to them [3–5,7–11]. Incident reporting systems, like the England and Wales National Reporting and Learning System (NRLS)<sup>2</sup>, include a range of patient safety incident types, specifically descriptions of, “any untoward incident that may or may not have led to harm” and invite free text descriptions of what happened, perceived potential contributory factors and actions to prevent future occurrence. Examination of report content can support the design of learning interventions to mitigate future events [12,13].

We aimed to characterize the nature and severity of immunization-related patient safety incidents involving children in primary care in England and Wales, in order to: identify priority issues for improvement; and generate hypotheses about change ideas that could form the basis of improvement recommendations and interventions.

## 2. Method

### 2.1. National reporting and learning system

The NRLS<sup>2</sup> is a national reporting system that collates locally generated reports that are received from healthcare organizations throughout England and Wales. The NRLS was launched in 2003 and receives approximately 100,000 reports a month, the majority written by healthcare professionals. It receives over 65,000 reports per annum involving children [13]. Reporting patient safety incidents that resulted in severe harm or death of a patient became mandatory in June 2010; however, before this all reporting was voluntary, and reporting remains voluntary for incidents resulting in no, low, or moderate harm [14,15].

Each report contains categorical information about location, patient age, incident type, and reporter perception of harm severity – collected in a structured report form – as well as free-text descriptions of the incident [14,15].

### 2.2. Sample selection

Over 20,000 pediatric, primary care-related incidents are present in the NRLS. Immunization-related safety incidents were identified by free-text key term searches, which we have found to generate both a sensitive and pragmatic means for identifying reports. Search terms and their permutations were

informed by brand and generic vaccine names from the British National Formulary and by an analysis of a pilot sample of over 600 immunization-related reports [10,16]. We included any immunization-related safety incidents occurring in primary care involving a child aged under-18 years between 2002 and 2013.

### 2.3. Data coding

Incident report free text was read and codes were applied to describe incident type, potential contributory factors, harm severity, and incident outcomes. The ‘Recursive Model of Incident Analysis’ method was used as a set of rules for applying codes in a chronological order (Supplement 1) [17]. This permitted modeling of the sequence of events leading to the primary incident type that resulted in the outcome experienced by the patient (Supplement 2). A ‘severity of harm’ had already been assigned to each report by the reporter; based on our interpretation of the report content, the severity of harm was re-classified using definitions from the WHO International Classification of Patient Safety when required (Table 1) [18]. Generic and brand names of vaccines were recorded. Incident types were independently double coded for a random 20% sample of reports (PR and HPE) with 3rd person arbitration (ACS) when necessary.

### 2.4. Data analysis

Relationships between codes were examined using frequency distributions and cross-tabulations. Two-way cross-tabulations were generated between age, incident type, vaccine type and contributory factors, compared to harm. Associations between these were examined using the Fisher’s exact test. To adjust for confounding of vaccine type on the effect of incident type on harm severity, a Mantel Haenszel adjusted approach was taken by stratifying vaccine and incident type.

### 2.5. Thematic analysis

Reports that contained the most frequently occurring incident type or contributory factor codes were re-read to generate additional insights and interpretations about those incidents and the kind of contexts in which they occurred [12]. Qualitative data software (NVIVO 9, QSR International) was used to independently analyze the reports and create new codes to capture this information. Themes that helped support our understanding of those incidents, and why they might have occurred, were agreed between PR and ACS [12,19].

### 2.6. Ethical approval

Aneurin Bevan University Health Board research risk review committee waived the need for ethical review given the anonymized nature of these data (ABHB R and D Ref number: SA/410/13).

## 3. Results

### 3.1. Characteristics of reports

Free-text searches identified 2298 reports, of which 1745 were included. Reports were excluded if they: were not immunization-error related ( $n=464$ ), e.g. describing a child who had received appropriate immunizations; contained insufficient free text ( $n=24$ ); or described issues that did not result in a patient safety incident ( $n=65$ ). Reports were submitted from 254 NHS providers in England and Wales, including 1052 reports from community nursing and 596 reports from general practice settings. Cohen’s

**Table 1**

The vaccines involved in reported incidents and the number of reports they are involved in (note: \*2 vaccines were involved in 1 child's death).

Vaccine	No harm	Low harm	Moderate harm	Death	Frequency (%)
Measles Mumps Rubella (MMR)	86	269	6	–	361 (18.2)
Pneumococcal conjugate (PCV)	140	160	4	3	307 (15.5)
Diphtheria tetanus acellular pertussis/inactivated polio/haemophilus influenza type B (DTaP/IPV/Hib)	97	142	1	1	241 (12.1)
Meningitis C (Men C)	103	122	1	–	226 (11.4)
Haemophilus influenza b/meningitis C (Hib/Men C)	70	123	2	–	195 (10)
Diphtheria tetanus acellular pertussis/inactivated polio (DTaP/IPV)	29	145	1	–	175 (9)
Human papilloma virus (HPV)	52	59	14	–	125 (6)
Bacillus Calmette–Guérin (BCG)	42	52	7	–	101 (5)
Tetanus, diphtheria and inactivated polio (Td/IPV)	15	65	13	–	93 (5)
Haemophilus influenza b (Hib)	13	37	–	–	50 (3)
Hepatitis B	24	10	7	–	41 (2)
Hepatitis A	10	11	0	–	21 (1)
Influenza	11	8	1	–	20 (1)
Other	6	9	1	–	16 (1)
Rotavirus	5	2	–	–	7 (0)
Typhoid	2	4	–	–	6 (0)
Total	705	1218	58	4*	1985 (100)

Definitions of Harm: No harm—patient outcome is not symptomatic and no treatment is required; Low harm—patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal and intermediate but short term, and no or minimal intervention is required; Moderate harm—patient outcome is symptomatic requiring intervention, an increased length of stay, or causing permanent or long-term harm or loss of function; Severe harm—patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function; and, Death—on balance of probabilities, death was caused or brought forward in the short term by the incident.

kappa statistic of inter-rater (coding) reliability was high,  $k = 0.77$ ,  $p < 0.001$ .

Most reports involved children aged less than three years old ( $n = 952$ , 55%) and peaks in frequency occurred, as expected, within the age groups children receive most vaccinations. Tables 1 and 2 highlight the most commonly cited vaccines and their associated harm severity outcomes. Most reports ( $n = 1135$ , 65%) described outcomes, which included: patient inconvenience ( $n = 801$ , 45.9%) such as receiving unnecessary treatment ( $n = 481$ , 27.6%) and requiring additional treatment ( $n = 379$ , 21.7%); clinical patient harm ( $n = 205$ , 11.7%) such as injuries ( $n = 72$ , 4%); and exposing the patient to risk ( $n = 139$ , 8%), for example by leaving them vulnerable to immunization preventable diseases ( $n = 108$ , 6%).

Administration was the most frequent incident type ( $n = 1282$ , 73.5%), with 'wrong number of doses', 'wrong timing', and 'wrong vaccine' described in ( $n = 1019$ , 79.5%) of those reports (Table 2). These are analyzed in further detail below.

There was a strong association between the type of administration-related incident and harm ( $p < 0.001$ ) and the type of vaccine and harm ( $p < 0.001$ ). After stratification into both 'incident' and 'vaccine' strata there was an association between type of administration incident and harm (in all vaccine strata  $p < 0.001$ ), thus vaccine type did not explain the varied risk of reported harm.

### 3.2. Administration of the wrong number of doses

Children who received the wrong number of doses were typically under six years old, most frequently (less than two years old  $n = 141$ , 30%), and typical vaccines implicated included Measles Mumps Rubella (MMR) ( $n = 156$ , 33%), Diphtheria Tetanus acellular Pertussis/Inactivated Polio (DTaP/IPV) ( $n = 87$ , 18%), and Haemophilus influenza b/Meningitis C (Hib/Men C) ( $n = 77$ , 16%) (Table 4). Reports frequently described harm ( $n = 448$ , 94.1%), typically because the child received unnecessary additional

vaccinations—a low harm event (Example 3.1, Table 3). One incident resulted in an adverse reaction necessitating a hospital admission—a moderate harm. There was no evidence to suggest association between vaccine type and harm ( $p = 0.49$ ) within this stratum (wrong number of doses).

Such incidents were frequently the result of prior incidents involving documentation failures ( $n = 188$ , 40%), including documentation not being up to date ( $n = 128$ , 27%), available ( $n = 45$ , 9%), or accurate ( $n = 15$ , 3%) (Examples 3.1–3.3, Table 3; Supplement 2). Additional associated incidents included administration of the wrong vaccine ( $n = 49$ , 10%), communication failures ( $n = 26$ , 5%), and difficulties making appointments ( $n = 19$ , 4%).

Table 5 presents the contributory factors described. Patient and parent contributory factors included: inadequate knowledge ( $n = 40$ , 8%), for example not being aware of which vaccines were needed or had previously been received; being new to the area or family practice ( $n = 36$ , 8%); and eight incidents (2%) were partly the result of a child being in 'out-of-home' care (e.g. foster care) (Examples 3.2 and 3.3, Table 3). Staff factors included: not following a protocol ( $n = 60$ , 13%), for example not checking the medical records before administration; and mistakes ( $n = 67$ , 14%) such as misreading vaccine names ( $n = 10$ , 2%).

### 3.3. Administration at the wrong time

Vaccines administered at the wrong time ( $n = 294$ , 16.8%) were typically described as deviating from the recommended national immunization schedule. Most children were aged under 1 year old ( $n = 175$ , 60%). Vaccines typically involved were Pneumococcal conjugate (PCV) ( $n = 91$ , 31%), Diphtheria Tetanus acellular Pertussis/Inactivated Polio/Haemophilus influenza type B (DTaP/IPV/Hib) ( $n = 83$ , 28%), and the MMR ( $n = 48$ , 16%) (Table 4). There was no evidence to suggest an association between vaccine type and harm ( $p = 0.51$ ) within this stratum (wrong time).

Of 55 (19%) harmful incidents, eight incidents resulted in moderate harm—typically these reports described delayed prophylactic

**Table 2**

The frequency and severity of harm described for each age group and for each primary incident type (N.B. this table does not include the frequencies of contributory incidents).

	Severity of harm				Frequency (%)
	No harm	Low harm	Moderate harm	Death	
Age					
Under 28 days	15	7	3	–	25 (1)
1 month to 1 year	307	246	13	3	569 (32.6)
2 to 4 years	206	433	9	–	648 (37.1)
5 to 11 years	41	133	5	–	179 (10)
12 to 17 years	99	188	37	–	324 (18.6)
Incident type					
Vaccination					
Administering	438	824	17	3	1282 (73.5)
Wrong number of doses	28	447	1	–	476
Wrong timing	239	44	8	3	294
Wrong vaccine	97	150	2	–	249
Not administered	14	65	1	–	80
Wrong dose	26	31	–	–	57
Expired vaccine	3	46	–	–	49
Non-specific	10	13	–	–	23
Contraindicated vaccine	14	5	1	–	20
Wrong patient	2	14	–	–	16
Wrong site	1	2	3	–	6
Used needle	3	2	–	–	5
Wrong storage	–	4	–	–	4
Wrong route	1	1	1	–	3
Adverse reaction	–	103	43	–	146 (8)
Prescribing and dispensing	26	–	–	–	26 (1)
Reconstitution error	–	4	–	–	4 (0)
Batch recall	4	–	–	–	4 (0)
Insufficient supply	1	–	–	–	1 (0)
Non-specific	1	–	–	–	1 (0)
Documentation	97	5	1	–	103 (6)
Records not up to date	62	3	1	–	66
Records inaccurate/unclear	29	2	–	–	31
Record availability	6	–	–	–	6
Administration	50	4	2	–	56 (3)
Appointment management	36	3	–	–	39
Transfer of information	12	1	2	–	15
Other	2	–	–	–	2
Procedural skills	4	53	–	–	57 (3)
Communication	44	9	–	–	53 (3)
With patients or parents	42	9	–	–	51
Between HCPs	2	–	–	–	2
Other	3	5	4	–	12 (1)
<b>Total</b>	<b>668</b>	<b>1007</b>	<b>67</b>	<b>3</b>	<b>1745 (100)</b>

administration of Hepatitis B and Bacillus Calmette–Guérin (BCG) vaccines to high-risk newborns. Three other incidents of delayed vaccination—contrary to the national recommended schedule—were potentially implicated in child deaths from meningitis and pneumonia, (Example 3.4, Table 3). Reports describing low harm outcomes typically described children who required additional vaccinations for adequate immunity. Timing-related vaccine incidents were preceded by incidents involving: appointment management ( $n = 60$ , 20%), documentation failures ( $n = 31$ , 11%), communication failures ( $n = 21$ , 7%), transfer of documentation ( $n = 16$ , 5%), and other vaccine-related incidents such as administration of the wrong vaccine ( $n = 12$ , 4%) (Supplement 2).

Table 5 highlights contributory factors implicated in these incidents such as: failure to follow protocol ( $n = 32$ , 11%); poor continuity of care ( $n = 22$ , 7%), for example community nurses not receiving birth notifications from secondary care; and staff mistakes ( $n = 22$ , 7%) (Examples 3.4–3.7, Table 3).

### 3.4. Administration of the wrong vaccine

Administration of the wrong vaccine was described in 249 reports (14.3%) and they were largely given to children under one year old ( $n = 121$ , 49%). Of these, 152 (61%) incidents resulted in harm, typically because children received unnecessary vaccinations and required additional treatment i.e. the vaccine that was

originally required. For example reports described administration of a Hib/Men C combination vaccine ( $n = 31$ , 12%) when a single (non-combination) Meningococcal C (Men C) vaccine was scheduled. Men C ( $n = 87$ , 35%), PCV ( $n = 85$ , 34%), and Hib/Men C ( $n = 61$ , 25%) vaccines were frequently implicated (Table 4). These incidents were rarely preceded by other incidents; however 18 (7%) resulted from documentation failures, and six (2%) resulted from immunizing the wrong child (Example 3.8, Table 3; Supplement 2). Within this stratum (wrong vaccine) there was strong evidence for an association between vaccine type and harm ( $p < 0.001$ ).

Contributory factors described were: staff issues which included mistakes ( $n = 87$ , 35%) such as confusing vaccines with similar names or appearances ( $n = 37$ , 15%) and failure to follow protocols ( $n = 35$ , 14%), such as concurrently preparing vaccines for multiple children (Example 3.9, Tables 3 and 5).

### 3.5. Overarching themes—Responsibility and vulnerability

Many reports implied parents were partly responsible for the occurrence of incidents, for example if the parent did not bring parent-held records to appointments or did not provide accurate medical histories (Example 3.3, Table 3). An underlying expectation that parents should be aware of their child's immunization needs and history was apparent. However parents appeared to have similar expectations of, and confidence that, healthcare professionals



**Table 3**

Edited extracts from incident reports.

Wrong number of doses

Example 3.1: Patient presented with **stepmother** for pre-school booster. Written **consent** from **father** was brought but **parental held record** was **not available**. Nurse explained she was giving **repevax** and **MMR**. The following day stepmother called expressing concern that **MMR** had **already been given** in 2004. **Incomplete documentation** of initial dose of MMR booster. (Low harm)

Example 3.2: Child placed with **adoptive parents** who were **advised** by **Social Worker** to attend physician to complete primary vaccinations. Attended surgery with parental held records but **no family practice records** were **available**. Only **two immunizations** were **recorded** in the parental held record. Immunization given with consent. Later informed by social services that child had **already completed** her **primary immunizations**. Family practice records checked and confirmed above. (Low harm)

Example 3.3: Patient received the third primary immunizations **twice** in error once in **Ghana** and once at the health center. Mother **failed to notify** the health visitor of the first immunization. (Low harm)

Wrong timing

Example 3.4: An infant died from a streptococcal pneumonia—which **could have been prevented** if the child had received childhood immunizations. The mother stated she was **not aware** that her child should be immunized and the child was **not registered** at a family practice until \*\*\* Identified areas of concern include: the management of the child immunization processes, family practice **registration processes** and **notifying** child health of **non-registered** patients. (Death)

Example 3.5: Patient's mother rang after receiving birthday card for child and realizing that her daughter had **not received an immunization appointment** since **transferring into the area**. Child health still had old address and old family practice details. Mother told to book immunization appointments with new family practice. (No harm)

Example 3.6: Patient's relative contacted health visitors regarding her child's immunizations, she reported she had **not received any appointments** for her child's third primary immunizations. **Child health** computer had **recorded wrongly** that the child had his third immunizations on the same day as he had his second immunizations. The patient **received** his third primary **immunizations late** because of this. Child health would not have been aware of this if the **parent** had not **contacted the service**. (No harm)

Example 3.7: Patient was scheduled for Hib/Men C vaccine, staff checked his immunization record and became aware that he already had this immunization. At this point **I made an error**. I told the mother that we could give the MMR/Prevenar. **Mother's English is not perfect** and she agreed. As I came to record the immunization, I realized my error there was a two-week gap between immunizations not 4. (No harm)

Wrong vaccine

Example 3.8: I was covering an immunizations session where normally there are 2 immunizers, the 2nd immunizer was sent home sick ten minutes prior to the start of the session. The healthcare assistant went to get the child and the mother for the immunization. The **wrong immunization** was **administered** to the child as we had the **paperwork for a different child**. The error was realized immediately, the child received Hib/Men C and MMR instead of 5 in 1 and Men C. (Low harm)

Example 3.9: Mother took her five-month-old baby to her family physician for his second DTaP/IPV/Hib vaccination. The staff nurse administered the **wrong injection** because she **did not consult his medical records**. The baby was given an MMR vaccination that should not be given until he is 13 months old. Staff Nurse says she was **distracted** during the appointment. The Nurse will **re-train** and demonstrate her competency through supervision. (Low harm)

Vulnerable child

Example 3.10: Baby received routine immunizations in baby clinic. The baby's consultant had written to the family physician requesting that the baby **not receive immunizations** until he is **one-year post chemotherapy**. Mother **believed** baby **should have immunizations** as he had received two flu vaccines between two sessions of chemotherapy previously. Family physician had seen this letter and had put a note on baby record but the **note was not dated** and believed to be an automatic warning. (No harm)

should be aware which immunizations their child required (Example 3.7, Table 3).

Collaboration between healthcare professionals and parents was reported as preventing some near-miss immunization-related safety incidents. There were reports detailing how parents had mitigated harm and prevented incidents by advocating for their children, chasing appointments, informing staff when the wrong vaccine was prepared, or reminding staff when a vaccine was contraindicated (Examples 3.5 and 3.6, Table 3). Lack of this parental safety net could be a factor in the immunization-related incidents described in children in 'out-of-home' care.

Socially vulnerable children such as those in 'out-of-home' care, and children of immigrant or traveller families, were described as experiencing incidents as a result of difficulty accessing care, poor continuity of care, and documentation failures. Accessing appropriate care was difficult for those vulnerable children for a range of reasons, including language barriers and inadequate parental knowledge of the need for vaccination or how to access primary care services, and in one case a child died (Example 3.4, Table 3).

Medically vulnerable children such as pregnant adolescents, those at risk of TB, Hepatitis B or HIV, or immunocompromised children, who required additional vaccinations or had contraindications to certain vaccines, were commonly represented in these reports. Numerous factors featured across those incident reports including: communication failures with children and parents; non-disclosure of medical conditions; non-adherence to the advice that parents were given by pediatricians; and poor staff and parent knowledge of vaccine contraindications in certain medical conditions (Example 3.10, Table 3).

#### 4. Discussion

This study has shown that the types of immunization-related safety incidents experienced by children are consistent with studies undertaken in other countries. Safer immunization is a priority area for quality improvement, which should focus on administering the correct vaccine, the correct number of times, and at the correct time for all children, and the timely and correct immunization of

**Table 4**

the vaccines involved in the most frequently reported incident types and their frequencies.

Type of administration incident	Vaccines														Total
	MMR	PCV	DTaP/IPV/Hib	Men C	Hib/Men C	DTaP/IPV	HPV	BCG	Td/IPV	Hib	Hepatitis B	Other	Hepatitis A	Influenza	
Wrong number of doses	156	75	63	49	77	87	8	20	36	16	–	5	3	1	596
Wrong timing	48	91	83	37	29	7	16	14	2	2	21	6	1	–	357
Wrong vaccine	41	85	56	87	61	49	8	3	23	1	1	5	6	4	430
Not administered	12	2	5	13	4	3	1	6	1	28	1	–	1	–	77
Wrong dose	12	1	1	7	3	1	2	9	–	–	5	1	5	3	50
Expired vaccine	12	–	1	2	4	7	1	5	1	3	1	1	2	2	42
Contraindicated vaccine	2	1	–	1	–	2	–	5	1	–	–	2	–	2	16
Wrong patient	7	1	4	2	1	1	2	–	1	–	–	–	–	–	19
Other	2	5	2	3	4	1	2	5	–	–	2	3	–	2	31

**Table 5**

Frequency of described contributory factors (note: \*some reports described more than one type of mistake).

	Frequency (%)
Patient/parent factors	
Patient/parent behavior—the way in which patients or parents act or conduct themselves	74 (8)
Non-compliance	60
Non-disclosure	12
Other	1
Violence	1
Patient/parent geography—the area where patients live	64 (7)
New to area	62
Access difficulties	2
Patient health—factors relating to the patient's physical and mental wellbeing	37 (4)
Allergy	22
Non-specific	4
Disability	4
Immunocompromised	3
Abnormal coagulation	2
Pregnancy	2
Patient/parent knowledge—insufficient knowledge or inadequate application of knowledge	48 (5)
Out-of-home care—children not in the care of their parents e.g. in foster care	18 (2)
Patient/parent language—patient or parent unable to communicate in English	5 (1)
Staff factors	
Mistake—cognitive lapses	*240 (25.2)
Non-specific mistake	139
Similar vaccine appearances	45
Distraction	22
Misreading	18
Inattention	10
Similar patient names	9
Failure to follow protocol—not adhering to organizational guidelines	186 (20)
Knowledge—insufficient knowledge or inadequate application of knowledge	19 (2)
Fatigue/stress—extreme tiredness, mental or emotional strain	5 (1)
Other factors	3 (0)
Equipment/vaccine factors	
Failure of equipment/vaccine—the equipment or vaccine is faulty	36 (4)
Equipment/vaccine packaging—the packaging is impractical inadequate or faulty	25 (3)
Equipment/vaccine storage—inadequate impractical storage	25 (3)
Poor equipment/vaccine design—the design is impractical, inadequate or faulty	3 (0)
Organizational factors	
Working Conditions—factors relating to the work environment	52 (5)
Continuity of care—issues with the co-ordination of services	48 (5)
Education and training—insufficient education and training of staff	36 (4)
Inadequate guidelines or protocols—existing guidelines not fit for purpose	27 (3)
Total	951 (100)

medically and socially vulnerable children. Crosscutting reported contributory factors for quality improvement interventions include staff mistakes, coordination and verification procedures, and parents' and staff knowledge and consequent behaviors.

#### 4.1. Strengths and limitations

This is the largest examination of reported contributory factors for immunization-related patient safety incidents in children. Incident report data are prone to numerous and well-acknowledged

biases including under-reporting and selective deposit bias [20]. For example, although the NRLS accepts reports from patients and parents, such reports were not apparent in our dataset. Further, there was likely differential reporting between organizations, those with good reporting cultures likely contribute more than those without such cultures [21].

Methodological rigor was ensured by keeping an audit trail of all coding-related decisions, holding weekly meetings to discuss analysis, and independent double-coding of 20% of reports indicating a high degree of concordance [22]. Our findings are hypothesis generating, inductive in nature, and require testing and development in further research and future clinical practice.

#### 4.2. Reviewing these findings in the context of other literature

High numbers of reports describing administration of the wrong number of doses was expected because they are usually apparent to those involved (the healthcare professional, patient or parent) and thus more likely to be reported. Previous studies investigating immunization-related safety incidents mirror our findings and demonstrate receipt of additional vaccines is a widespread problem often resulting from poor documentation e.g. where a child is immunized but this goes undocumented resulting in that child receiving that same vaccine later [4,7,23]. In one U.S. study, over 20% of children received unnecessary duplicate vaccinations [4].

Our data contained reports of delayed vaccination or receipt of vaccines out-of-schedule with the national immunization schedule. Experts determine the vaccination schedule to afford children maximum protection from diseases and to minimize the risk of vaccine interaction. The consequences of deviating from this schedule are unclear [7,24,25].

Wrong vaccine administration is a recognized issue [7,23,26,27]. Children who receive the wrong vaccine, but in whom the error goes undetected could be both under-protected and at risk since their inadequate immunity would be unrecognized [7,23]. The potentially severe consequences of immunization-related safety incidents in medically vulnerable children have also been highlighted by other studies [28,29].

Socially vulnerable children were commonly represented in this sample and the inverse care law, where those most in need of high quality care are the least likely to receive it, is evident in this context [30]. Poorer vaccination uptake in vulnerable children is described in the literature [31–33], yet the challenges of conducting research with marginalized populations could perhaps explain the limited interventional efforts to date [34].

#### 4.3. Recommendations for improvement

Continued efforts by manufacturers to create vaccines with different packaging and distinguishable names are needed [35,36].

Our findings support targeted community nurse visits to socially vulnerable children [37], to educate parents about the need for timely vaccination, and to encourage vaccine uptake. In addition, providing parents with access to all of their children's records could reduce documentation discrepancies and appointment-related incidents, as well as provide healthcare professionals with a safety net [38]. This could also be enhanced with better accessibility of unified immunization records for staff [39]. Building IT infrastructure and functionality capable of sharing data between health and social care providers could support identification of predictors of risk and inform interventions to mitigate future incidents [40].

Encouraging parental involvement, and creating a culture where parents feel comfortable challenging healthcare professionals, could also prevent safety incidents [38]. Co-production methods, where patients and providers co-design new models and methods of care delivery could be used to inform local improvement

initiatives that advance this parent–provider relationship for child safety [41–43]. Public health organizations and researchers must seek to establish what methods of communication work best for different patient and parent groups, and embrace the challenge of undertaking research with and for marginalized patient populations.

To reduce staff mistakes, locally-owned efforts to adopt and adapt best practices proven to be effective elsewhere should be explored for verification and standardized preparation of vaccines [36,44].

## 5. Conclusions

The types of immunization-related safety incidents experienced by children in England and Wales are consistent with those described in studies undertaken in other countries. This is the largest examination of reported contributory factors for immunization-related patient safety incidents in children, and based on this analysis we have made a number of priority recommendations for policy, practice, and research. These include: investments in IT infrastructure to support data linkage and the identification of risk predictors; development of consultation models to enhance parental roles in mitigating safety incidents; and improvement efforts to adapt and adopt best practices from elsewhere. These priorities are particularly pressing for medically and socially vulnerable patients.

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## Contributor statements

Ms Rees was responsible for primary data coding, qualitative analysis, interpretation of results, and drafting the manuscript. Professor Edwards conceptualized and designed the study. He carried out interpretation of the results, created the recommendations for practice and reviewed the manuscript. Dr Powell provided the clinical interpretation of results, creation of recommendations for pediatric practice, and reviewed the manuscript. Dr Carter was the study statistician and responsible for data analysis, and interpretation of the results and reviewed the manuscript. Dr Evans was the project clinical informatics lead and responsible for development of the data storage infrastructure, clinical interpretation of results and creating recommendations for improvement. Mr Hibbert conceptualized and designed the study and development of the in-house classification systems. He interpreted the results and reviewed the manuscript. Dr Makeham contributed to the clinical interpretation of results, creation of recommendations for family practice, and reviewed the manuscript. Professor Sheikh conceptualized and designed the study interpretation of results, and reviewed the manuscript. Professor Donaldson conceptualized and designed the study interpretation of results, and reviewed the manuscript. Dr Andrew Carson-Stevens conceptualized and designed the study. He was responsible for data coding, qualitative analysis,

interpreting results, developing recommendations for clinical practice, and revising the manuscript. He is also the study guarantor. All co-authors approved the final manuscript as submitted.

## Conflict of interest statement

ACS and AE are co-chief investigators, and AS and LD are co-applicants on a NIHR HS&DR funded study to characterize primary care patient safety incident reports.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.vaccine.2015.06.068>

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